



10-14-03

WSHU 2047.1
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Pampee P. Young et al.

Serial No. 10/616,821

Filed July 10, 2003

For PROMOTION OF NEOVASCULARIZATION USING BONE MARROW-DERIVED
ENDOTHELIAL-PROGENITOR CELLS

October 10, 2003

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VIRGINIA 22313-1450

SIR:

INFORMATION DISCLOSURE STATEMENT

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit copies of the references listed on the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the waiver of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Applicants submit herewith copies of references Nos. 16-60 which are either foreign patent documents or literature references.

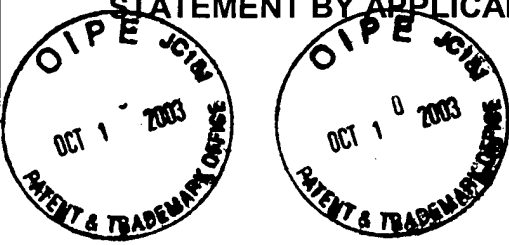
This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicants believe that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required.

Respectfully submitted,

Edward J. Hejlek, Reg. No. 31,525
SENNIGER, POWERS, LEAVITT & ROEDEL
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102
(314) 231-5400

EJH/AXS/vlm

Express Mail Label No. **EL 998648587 US**

PTO/SB/08A				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT 				Application Number	10/616,821
				Filing Date	July 10, 2003
				Confirmation Number	
				First Named Inventor	Pampee P. Young
				Group Art Unit	
				Examiner Name	
Sheet	1	of	6	Attorney Docket No.	WSHU 2047.1


U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	1	4,394,448		Szoka, Jr. et al.	07-19-1983
	2	5,139,941		Muzyczka et al.	08-18-1992
	3	5,199,942		Gillis, S.	04-06-1993
	4	5,399,346		Anderson et al.	03-21-1995
	5	5,436,146		Shenk et al.	07-25-1995
	6	5,622,856		Natsoulis, G.	04-22-1997
	7	5,665,577		Sodroski et al.	09-09-1997
	8	5,672,510		Eglitis et al.	09-30-1997
	9	5,676,954		Brigham, K.L.	10-14-1997
	10	5,707,865		Kohn et al.	01-13-1998
	11	5,817,491		Yee et al.	10-06-1998
	12	5,910,434		Rigg et al.	06-08-1999
	13	5,980,887		Isner et al.	11-09-1999
	14	5,994,136		Naldini et al.	11-30-1999
	15	6,013,516		Verma et al.	01-11-2000

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A INFORMATION DISCLOSURE STATEMENT BY APPLICANT 				Complete if Known	
				Application Number	10/616,821
				Filing Date	July 10, 2003
				Confirmation Number	
				First Named Inventor	Pampee P. Young
				Group Art Unit	
				Examiner Name	
Sheet	2	of	6	Attorney Docket No.	WSHU 2047.1


FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁶
		Office	Number ⁴	Kind Code ² (if known)			
	16	WO	96/18418	A1	Genetic Therapy, Inc.	06-20-1996	
OTHER ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁶
	17	AGARWAL, M. et al., Scaffold Attachment Region-Mediated Enhancement of Retroviral Vector Expression in Primary T Cells, Journal of Virology, (1998), pp. 3720-3728, Vol. 72:5					
	18	ASAHARA, T. et al., Bone Marrow Origin of Endothelial Progenitor Cells Responsible for Postnatal Vasculogenesis in Physiological and Pathological Neovascularization, Circulation Research, (1999), pp. 221-228, Vol. 85					
	19	ASAHARA, T. et al., Isolation of Putative Progenitor Endothelial Cells for Angiogenesis, Science, (1997), pp. 964-967, Vol. 275					
	20	ASAHARA, T. et al., VEGF Contributes to Postnatal Neovascularization by Mobilizing Bone Marrow-Derived Endothelial Progenitor Cells, The EMBO Journal, (1999), pp. 3964-3972, Vol. 18:14					
	21	BERKNER, K.L., Development of Adenovirus Vectors for the Expression of Heterologous Genes, BioTechniques, (1988), pp. 616-628, Vol. 6:7					
	22	BORDIGNON, C. et al., Gene Therapy in Peripheral Blood Lymphocytes and Bone Marrow for ADA - Immunodeficient Patients, Science, (1995), pp. 470-475, Vol. 270					
	23	BOYER, M. et al., Isolation of Endothelial Cells and Their Progenitor Cells from Human Peripheral Blood, Journal of Vascular Surgery, (2000), pp. 181-189, Vol. 31:1/1					

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT 				Application Number	10/616,821
				Filing Date	July 10, 2003
				Confirmation Number	
				First Named Inventor	Pampee P. Young
				Group Art Unit	
				Examiner Name	
Sheet	3	of	6	Attorney Docket No.	WSHU 2047.1


	24	CEPKO, C.L. et al., Construction and Applications of a Highly Transmissible Murine Retrovirus Shuttle Vector, Cell, (1984), pp. 1053-1063, Vol. 37:3	
	25	CHARTIER, C. et al., Efficient Generation of Recombinant Adenovirus Vectors by Homologous Recombination in <i>Escherichia coli</i> , Journal of Virology, (1996), pp. 4805-4810, Vol. 70:7	
	26	CRISA, L. et al., Human Cord Blood Progenitors Sustain Thymic T-Cell Development and a Novel Form of Angiogenesis, Blood, (1999), pp. 3928-3940, Vol. 94:11	
	27	DESNICK, R.J. et al., Fabry Disease (α -Galactosidase A Deficiency): Renal Involvement and Enzyme Replacement Therapy, Contributions to Nephrology, (2001), pp. 174-192, Vol. 136	
	28	DUNBAR, C. et al., Retroviral Mediated Transfer of the cDNA for Human Glucocerebrosidase into Hematopoietic Stem Cells of Patients with Gaucher Disease. A Phase I Study, Human Gene Therapy, (1996), pp. 231-253, Vol. 7	
	29	DUNBAR, C.E. et al., Retrovirally Marked CD34-Enriched Peripheral Blood and Bone Marrow Cells Contribute to Long-Term Engraftment After Autologous Transplantation, Blood, (1995), pp. 3048-3057, Vol. 85:11	
	30	FERRARA, N. et al., Clinical Applications of Angiogenic Growth Factors and Their Inhibitors, Nature Medicine, pp. 1359-1364, Vol. 5:12	
	31	FORESTELL, S.P. et al., Novel Retroviral Packaging Cell Lines: Complementary Tropisms and Improved Vector Production for Efficient Gene Transfer, Gene Therapy, (1997), pp. 600-610, Vol. 4	
	32	FREEMAN, B.J. et al., Behavior and Therapeutic Efficacy of β -Glucuronidase-Positive Mononuclear Phagocytes in a Murine Model of Mucopolysaccharidosis Type VII, Blood, (1999), pp. 2142-2150, Vol. 94:6	
	33	HANANIA, E.G. et al., Results of MDR-1 Vector Modification Trial Indicate that Granulocyte/Macrophage Colony-Forming Unit Cells Do Not Contribute to Posttransplant Hematopoietic Recovery Following Intensive Systemic Therapy, Proc. Natl. Acad. Sci., (1996), pp. 15346-15351, Vol. 93	
	34	HE, T-C et al., A Simplified System for Generating Recombinant Adenoviruses, Proc. Natl. Acad. Sci., (1998), pp. 2509-2514, Vol. 95	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A INFORMATION DISCLOSURE STATEMENT BY APPLICANT 				Complete if Known	
				Application Number	10/616,821
				Filing Date	July 10, 2003
				Confirmation Number	
				First Named Inventor	Pampee P. Young
				Group Art Unit	
				Examiner Name	
Sheet	4	of	6	Attorney Docket No.	WSHU 2047.1


	35	HIGH, K.A., Gene Transfer as an Approach to Treating Hemophillia, Circulation Research, (2001), pp. 137-144, Vol. 88	
	36	ISNER, J.M. et al., Angiogenesis and Vasculogenesis as Therapeutic Strategies for Postnatal Neovascularization, The Journal of Clinical Investigation, (1999), pp. 1231-1236, Vol. 103:9	
	37	KADHOM, N. et al., Factor VIII Procoagulant Antigen in Human Tissues, Thrombosis and Haemostasis, (1988), pp. 289-294, Vol. 59:2	
	38	KALKA, C. et al., Transplantation of ex vivo Expanded Endothelial Progenitor Cells for Therapeutic Neovascularization, Proc. Natl. Acad. Sci., (2000), pp. 3422-3427, Vol. 97:7	
	39	KAPPEL, A. et al., Identification of Vascular Endothelial Growth Factor (VEGF) Receptor-2 (<i>Flk-1</i>) Promoter/Enhancer Sequences Sufficient for Angioblast and Endothelial Cell-Specific Transcription in Transgenic Mice, Blood, (1999), pp. 4284-4292, Vol. 93:12	
	40	KIM, T.H. et al., Total-Body Irradiation with a High-Dose-Rate Linear Accelerator for Bone-Marrow Transplantation in Aplastic Anemia and Neoplastic Disease, Radiology, (1977), pp. 523-525, Vol. 122	
	41	LIN, H. et al., Long-Term Acceptance of Major Histocompatibility Complex Mismatched Cardiac Allografts Induced by CTLA4lg Plus Donor-Specific Transfusion, J. Exp. Med., (1993), pp. 1801-1806, Vol. 178	
	42	LIU, J.M. et al., Retroviral Mediated Gene Transfer of the Fanconi Anemia Complementation Group C Gene to Hematopoietic Progenitors of Group C Patients, Human Gene Therapy, (1997), pp. 1715-1730, Vol. 8	
	43	MALECH, H.L. et al., Prolonged Production of NADPH Oxidase-Corrected Granulocytes After Gene Therapy of Chronic Granulomatous Disease, Proc. Natl. Acad. Sci., (1997), pp. 12133-12138, Vol. 94	
	44	MANNUCCI, P.M., How I Treat Patients With von Willebrand Disease, Blood, (2001), pp. 1915-1919, Vol. 97:7	
	45	MARCHETTI, S. et al., Endothelial Cells Genetically Selected from Differentiating Mouse Embryonic Stem Cells Incorporate at Sites of Neovascularization In Vivo, Journal of Cell Science, (2002), pp. 2075-2085, Vol. 115	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


PTO/SB/08A				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT 				Application Number	10/616,821
				Filing Date	July 10, 2003
				Confirmation Number	
				First Named Inventor	Pampee P. Young
				Group Art Unit	
				Examiner Name	
Sheet	5	of	6	Attorney Docket No.	WSHU 2047.1

	46	MORISHITA, K. et al., A Novel Promoter for Vascular Endothelial Growth Factor Receptor (<i>flt-1</i>) That Confers Endothelial-Specific Gene Expression, The Journal of Biological Chemistry, (1995), pp. 27948-27953, Vol. 270:46	
	47	PEICHEV M. et al., Expression of VEGFR-2 and AC133 by Circulating Human CD34 ⁺ Cells Identifies a Population of Functional Endothelial Precursors, Blood, (2000), pp. 952-958, Vol. 95:3	
	48	PLAVEC, I. et al., High Transdominant RevM10 Protein Levels are Required to Inhibit HIV-1 Replication in Cell Lines and Primary T Cells: Implication for Gene Therapy of AIDS, Gene Therapy, (1997), pp. 128-139, Vol. 4	
	49	QIN, G. et al., Preselective Gene Therapy for Fabry Disease, Proc. Natl. Acad. Sci., (2001), pp. 3428-3433, Vol. 98:6	
	50	RIGG, R.J. et al., A Novel Human Amphotropic Packaging Cell Line: High Titer, Complement Resistance, and Improved Safety, Virology, (1996), pp. 290-295, Vol. 218	
	51	RONICKE, V. et al., Characterization of the Endothelium-Specific Murine Vascular Endothelial Growth Factor Receptor-2 (Flk-1) Promoter, Circulation Research, (1996), pp. 277-285, Vol. 79	
	52	SCHLAEGER, T.M. et al., Uniform Vascular-Endothelial-Cell-Specific Gene Expression in Both Embryonic and Adult Transgenic Mice, Proc. Natl. Acad. Sci., (1997), pp. 3058-3063, Vol. 94	
	53	SHENK, T. et al., Genetic Analysis of Adenoviruses, Microbiol. Immunol., (1984), pp. 1-39, Vol. 111	
	54	SHI, Q. et al., Evidence for Circulating Bone Marrow-Derived Endothelial Cells, Blood, (1998), pp. 362-367, Vol. 92:2	
	55	TUTSCHKA, P.J. et al., Bone Marrow Transplantation for Leukemia Following a New Busulfan and Cyclophosphamide Regimen, Blood, (1987), pp. 1382-1388, Vol. 70:5	
	56	VERES, G. et al., Comparative Analyses of Intracellularly Expressed Antisense RNAs as Inhibitors of Human Immunodeficiency Virus Type 1 Replication, Journal of Virology, (1998), pp. 1894-1901, Vol. 72:3	
	57	WALSH, C.E., Gene Therapy for the Hemophilias, Current Opinion in Pediatrics, (2002), pp. 12-16, Vol. 14	
	58	YEAGER, A.M. et al., Bone Marrow Transplantation for Infantile Ceramidase Deficiency (Farber Disease), Bone Marrow Transplantation, (2000), pp. 357-363, Vol. 26	
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A INFORMATION DISCLOSURE STATEMENT BY APPLICANT 				Complete if Known	
				Application Number	10/616,821
				Filing Date	July 10, 2003
				Confirmation Number	
				First Named Inventor	Pampee P. Young
				Group Art Unit	
				Examiner Name	
Sheet	6	of	6	Attorney Docket No.	WSHU 2047.1

	59	YOUNG, P.P. et al., VEGF Increases Engraftment of Bone Marrow-Derived Endothelial Progenitor Cells (EPCs) into Vasculature of Newborn Murine Recipients, Proc. Natl. Acad. Sci., (2002), pp. 11951-11956, Vol. 99:18	
	60	ZANJANI, E.D. et al., Prospects for in Utero Human Gene Therapy, Science, (1999), pp. 2084-2088, Vol. 285	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.